

BF



(19) Europäisches Patentamt  
 European Patent Office  
 Office européen des brevets



(11) Publication number:

0 450 341 B1

(12)

## EUROPEAN PATENT SPECIFICATION

(45) Date of publication of patent specification: 20.12.95 (51) Int. Cl.<sup>6</sup>: A61B 5/0496, A61B 5/0205,  
 A61B 5/0488, G06F 17/00,  
 A61B 5/0452, A61B 5/0402

(21) Application number: 91103601.0

(22) Date of filing: 08.03.91

## (54) Cardiac analyzer with rem sleep detection

(30) Priority: 05.04.90 US 505216

(43) Date of publication of application:  
 09.10.91 Bulletin 91/41

(45) Publication of the grant of the patent:  
 20.12.95 Bulletin 95/51

(84) Designated Contracting States:  
 DE FR GB NL

(56) References cited:  
 EP-A- 0 306 346  
 US-A- 4 228 806  
 US-A- 4 667 682

(73) Proprietor: Hewlett-Packard Company  
 Mail Stop 20 B-O,  
 3000 Hanover Street  
 Palo Alto,  
 California 94304 (US)

(72) Inventor: Forbes, Dean A.  
 820 Loma Verde Avenue  
 Palo Alto, CA 94303 (US)

(74) Representative: Schoppe, Fritz, Dipl.-Ing.  
 Patentanwalt,  
 Georg-Kalb-Strasse 9  
 D-82049 Pullach (DE)

EP 0 450 341 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

## Description

## BACKGROUND OF THE INVENTION

The present invention relates to medical instruments and, more particularly, to a system and method for detecting fractionated cardiac potentials. A major objective of the present invention is reliable characterization of fractionated cardiac potentials which can be a prodrome of sudden cardiac death.

Sudden cardiac death (SCD) is usually the result of primary electrical instability of the heart. This instability can result when compromised regions of a heart disrupt the electrical signal which activates the heartbeat. These disruptions, while not always fatal, cause fractionated potentials, which provide clues as to a subject's susceptibility to potentially fatal heart problems.

A fundamental challenge in cardiology is to obtain electrocardiograms which are sufficiently free of noise that fractionated potentials can be detected reliably. Being very weak signals, fractionated potentials occurring during electrically active periods of the heartbeat are readily masked by the much stronger cardiac signals. In addition, even when fractionated potentials occur during periods otherwise free of cardiac signals, they can be masked by non-cardiac electrical activity. If the electrical potentials associated with heartbeat activation are precisely registered and carefully processed, information about the fractionated potentials can be recovered reliably. Less careful acquisition and processing can allow the minuscule fractionated potentials to be missed.

Electrocardiograms are usually obtained non-invasively to minimize subject stress and inconvenience, as well as medical expense. Typically, cardiac electrical potentials are detected by electrodes on the body surface connected to an electrocardiograph (ECG) which plots the various potentials as a heartbeat waveform. The cardiac potentials at the electrodes are quite weak, in part, because of current-shunting by tissue between the heart and the skin surface.

The weakness of the monitored cardiac signals makes them vulnerable to noise. The noise can arise from stray electrical fields external to the subject and from non-cardiac fields within the subject. Most notably, electrical potentials from the subject's muscular activity and tonicity are superimposed on the cardiac potentials. This superposition makes it more difficult to obtain the accurate heartbeat waveforms required for reliable detection of fractionated potentials.

From an information theory perspective, the problem of accurate representations of electrocardiac activity corresponds to a need to improve the

signal-to-noise ratio for the cardiac potentials. Time-averaging is a well-known approach to improving the signal-to-noise ratio for a periodic waveform. When several successive single-cycle waveform segments are aligned and superimposed, the common components reinforce each other while random noise components tend to cancel. This approach has been used often in the detection of abnormal heartbeat patterns (arrhythmias). The arrhythmias can be detected by monitoring a subject over a long interval, making use of a compact, ambulatory ECG such as a Holter recorder.

The fractionated potentials associated with SCD are weaker than the potentials associated with arrhythmias detectable in Holter recordings, and additionally, they can fluctuate. Electrical signals that are shunted around abnormal regions of heart tissue along various routes generate variable electrical potentials at the skin surface. To the extent that the resulting fractionated potentials vary from heartbeat to heartbeat, they will be cancelled rather than enhanced by time-averaging. The achievement of signal-to-noise enhancement by time averaging when prospecting for fractionated potentials is debilitated by the irregularity of the fractionated potentials. In this circumstance, both noise and signal are reduced by time averaging.

Another approach to improving the signal-to-noise ratio of the ECG signals is to minimize the sources of noise. Relaxation techniques and shallow breathing techniques have been used to reduce muscular activity and thus the amount of noise contributed by electrical activity in the muscles. However, the noise reduction provided by these techniques is limited. Furthermore, these techniques require subject relaxation, which may not be achieved or sustained. The requirement of subject relaxation can limit the practical duration over which reliable monitoring can occur.

The duration over which monitoring can occur is important since fractionated potentials occur sporadically in some subjects. Thus, characterization of fractionated potentials can require monitoring a subject over many hours. The length of time required for monitoring a subject introduces another problem: the volume of electrical activity data generated by a subject over such an extended period can make it difficult to identify electrical patterns of interest. Thus, there is a need for some preselection of data to reduce the field of search for the cardiac events of interest.

What is needed is a system and method for detecting fractionated potentials so that a subject's risk of sudden cardiac death can be assessed with greater confidence than previous methods allow. This requires high-precision multichannel electrocardiograms obtained without using time-averaging techniques, which techniques can wash out irregu-

lar potentials. Provision for convenient monitoring of a subject over extended time periods is required to enhance the odds that fractionated potentials will be detected, yet the amount of data collected should be limited to an amount which can be practically examined for the fractionated potentials of interest.

#### SUMMARY OF THE INVENTION

In accordance with the present invention, cardiac electrical potentials are monitored intensively during rapid eye movement (REM) sleep and/or atypical autonomic nervous system drive. In the application of primary interest herein, a cardiac analyzer system includes means for detecting the occurrence of REM sleep or significant departures from average autonomic drive, and an electrocardiograph for monitoring and recording detailed cardiac activity. The REM sleep/autonomic drive detector means can include the ECG electrode sets or dedicated physiological sensors.

The electrocardiograph is coupled to the REM sleep/autonomic drive detector means so that the amount of electrocardiac data recorded is much greater during REM sleep than during other times. Since REM sleep occurs during only about one-fifth of an average sleep cycle, excluding all data outside the REM sleep state permits a 5:1 data reduction, greatly reducing the amount of data to be analyzed for diagnosing SCD potential and similar heart conditions. A computer controller can provide that electrocardiac data be stored only during REM sleep, atypical autonomic drive, and/or ischemia. Alternatively, the computer controller can provide that a limited amount of electrocardiac data be collected at all times, while additional channels of electrocardiac data be recorded only during REM sleep, atypical autonomic drive, and/or ischemia.

A preferred cardiac analyzer system provides for multiple channels of data. These include multiple electrocardiographic channels and can include channels dedicated to the physiological detection of REM sleep states. For example, eye movement sensors, muscle atonia sensors, or brain wave sensors can be used for REM sleep state detection. Multiple electrocardiographic channels are used in parallel to enhance signal-to-noise performance by spatial averaging of received signals. In addition, some channels are dedicated to monitoring environmental noise so that electromagnetic disturbances can be assessed and cancelled from the data channels. A preprocessor provides for baseline correction and spatial averaging for the multiple channels.

REM sleep is characterized by generalized muscle atonia so that noise due to muscular tone is

absolutely minimal. REM sleep is also characterized by extreme excursions of both the sympathetic and parasympathetic branches of the autonomic nervous system. Variations in autonomic drive level, in the form of bursts of autonomic nervous system activity, cause rapid heart rate accelerations and decelerations. Individuals susceptible to heart arrhythmias may respond with arrhythmic activity including ectopic beats. Elevated sympathetic stimulation has been shown to correlate with enhanced cardiac electrical instability. Thus, by monitoring subjects during REM sleep, the present invention collects cardiac data both when the events of interest are most likely to occur and when they are least likely to be masked by noise.

The time-varying autonomic drive to the heart has a critical role in inducing cardiac electrical instability. Therefore, cardiac electrical potentials are also analyzed during atypical autonomic drive. Autonomic drive levels can be estimated indirectly by analysis of the electromyographic signals on the electrocardiographic channels. The present cardiac analyzer may supplement the data on the electrocardiogram with data reflective of autonomic nervous system drive obtained from sensors.

Additionally, the ECG data are computer-analyzed to indicate the occurrence of myocardial ischemia, a lack of sufficient blood supply to the heart tissue, which provides another likely interval to observe fractionated potentials. Intense data collection is undertaken during myocardial ischemia.

The present invention provides for a method of characterizing cardiac performance in an individual comprising the steps of attaching a primary set of ECG electrode sets to an individual, optionally attaching dedicated physiological sensors of sleep state and autonomic drive, positioning electromagnetic interference (EMI) sensors near the individual, collecting primary ECG signal data from the electrode sets, sleep state and autonomic drive data from the physiological sensors, and EMI data from the EMI sensors, monitoring the collected data to detect either a REM sleep state or atypical autonomic fluctuations and, following such detection, initiating recording of the primary ECG signal data and the ancillary physiological signal data.

The multichannel electrocardiograph of the invention has the capability of differentiating non-repetitive very low amplitude electrical signals in the microvolt range from background noise. This high resolution capability is possible because of the maximum reduction of noise attendant with REM sleep. In addition, the present invention can be implemented as a compact, ambulatory unit which is non-restricting to the patient and thus convenient for usage at home. This is important because unfamiliar environments lead to suppres-

sion of REM sleep.

The present invention provides several advantages over the prior systems and methods. Cardiac electrical activity is monitored during a period in which fluctuating fractionated potentials indicative of cardiac electrical instability are most likely to appear. Periods less likely to produce fractionated potentials are excluded, greatly economizing on the amount of data storage required for a diagnosis. The use of spatial averaging of signals enhances the signal-to-noise ratio, and retains the time variations which are lost when time-averaging is used. Channels dedicated to EMI assessment allow data removal or correction for distortions of the electrocardiographic signals of interest. These and other features and advantages of the present invention are apparent from the description below with reference to the following drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a schematic diagram of one embodiment of the cardiac analysis system.

FIGURE 2 is a flow chart representing a method of the invention that can be implemented using the cardiac analysis system of FIG. 1.

FIGURE 3 is a block diagram of the cardiac analysis system of FIG. 1.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

In accordance with the present invention, a cardiac analyzer system 100 for assessing a subject 99 includes a computer 102, a data quality monitor 104, a remote front end (RFE) 106, a cable concentrator unit 108, electrode sets 110 and 112, and auxiliary physiological sensors 114, as shown in FIG. 1. Electrode sets 110 and 112 are attached to subject 99 for monitoring electrocardiographic, electromyographic, and respiratory activity. Sensors 114 are attached to subject 99 for monitoring sleep state. Additionally, electrode sets 110 and sensors 114 are used also to monitor autonomic drive levels. This enables the instrument to correlate fluctuating autonomic nervous system drive mechanisms with fluctuating ECG signals to derive information on fractionated potentials and cardiac electrical stability. In addition, sensors 116 are disposed near subject 99 for monitoring the ambient EMI noise levels. At-subject buffer amplifiers are provided for each ECG electrode set and each EMI sensor.

The signals transduced by electrode sets 110 as well as the dedicated signals provided by sensors 114 are used to detect the existence of a REM sleep state. When a REM sleep state is detected by computer 102, data from sensors 114

and 116 and electrode sets 110 and 112 are recorded for off-line analysis. In the absence of a REM sleep state, data from electrode sets 110 and from sensors 114 are not recorded unless fluctuating autonomic drive and/or ischemia are detected. The data from electrode sets 110 and 112 provide multiple channels of electrocardiac data which can be spatially averaged to improve signal-to-noise ratio. Sensors 116 provide environmental noise data which are used to gate out or purify corrupted data. This arrangement results in spatially-averaged low-noise data characterizing the cardiac activity of subject 99 during REM sleep.

More specifically, cardiac electrical signals at the body surface of subject 99 are transmitted via ten primary ECG electrode sets 110 and six secondary electrode sets 112 through ten leads 118 and six leads 120, respectively. Multiple leads 118 and 120 are collected into a manageable cable cluster 122 at concentrator unit 108 that is attached to a belt 124 worn by subject 99. Cable cluster 122 is connected through a quick release connector 125 to RFE 106, a unit positioned near the subject's bed. Furthermore, cable cluster 122 is long enough to permit subject 99 limited ambulation in the vicinity of RFE 106.

Primary ECG electrode sets 110 initiate a first set of data channels 126 and secondary ECG electrode sets 112 initiate a second set of data channels 128. Both sets of channels extend from their respective electrode sets, through RFE 106 to computer 102. RFE 106 includes an analog preprocessor 130 which contains amplifiers, impedance drives/decoders, offset bucking, and common-mode cancellation. Computer 102 implements a multichannel analysis to monitor lead quality, buck out electrode offsets, flag epochs of excessive EMI, form continuously-monitored signals, sense REM sleep, sense autonomic fluctuations, sense ischemia, and control data storage.

EMI from the environment is reduced by shielding subject 99 with a shielding blanket or shielding sleeping bag and by common-mode driving. However, interference that gets through the shielding is sensed by the three EMI sensors 116 which monitor this interference in three dimensions. EMI sensors 116 are placed off subject 99 but in close proximity to ECG electrode sets 110 and 112. The EMI signals are transmitted through leads 132 to RFE 106 and via a third set of data channels 134 to preprocessor 130 where they are amplified and processed along lines paralleling the handling of signals from electrode sets 110 and 112. When extremely noisy intervals occur which corrupt the ECG signals, computer 102 rejects the signals from that interval and halts recording until the EMI abates.

Converter 136 in RFE 106 performs analog to digital conversion, signal interleaving, and computer control execution. The ECG data are formatted by converter 136, are converted to light pulses and are transmitted through fiber optic cables 138 to computer 102. ECG data from the first set of channels 126 are recorded only during intervals of REM sleep or significant autonomic drive variation. Data from the second set of channels 128 are compressed and recorded throughout the monitoring interval. For off-line analysis, all data are recorded on data store 140 capable of storing large amounts of information. The data are optionally displayed on monitor 104, allowing quality-control by the operator.

The use of fiber optic cables 138 and RFE 106, which is battery powered, isolate subject 99 from power line voltages, such as those utilized by computer 102. Additionally, to accommodate hospital requirements, all system elements in contact with subject 99, such as electrodes 110 and 112, leads 118 and 120, concentrator 108, cable cluster 122, and belt 124 are capable of being sterilized.

Detection of REM sleep stage and assessment of autonomic drive status as well as myocardial ischemia are primarily accomplished through analysis of data channels 126 and 128. Additional channels of information are optionally available through sensors 114. Sensors 114 comprise electrodes of an electromyograph and an electro-occulograph, which monitor electrical signals from skeletal and periorbital muscles, respectively. Sensors 114 also comprise electrodes of an electroencephalograph which measures brain activity. Alternatively, other sensors for detecting REM sleep and autonomic nervous system drive levels can be used. Signals from these dedicated sensors are transmitted through sensor leads 142 to the remote front end unit 106. The signals are transmitted over a fourth set of signal channels 144 to preprocessor 130 and then to converter 136. When incoming signals indicate the atonic muscle state and/or rapid eye movements characteristic of REM sleep, the computer 102 initiates recording of the full complement of ECG channels as well as the signals from sensors 116 and 114. By saving full data only during intervals of REM sleep or significant autonomic nervous system drive variation, considerable data reduction is achieved, on the order of 5:1 for overnight monitoring.

Preamplifiers (not shown) are provided for each of the ECG electrodes 110 and 112 and sensors 114 and 116. These preamplifiers are characterized by very high gain, very low noise, wide bandwidth, and wide dynamic range. In addition, the preamplifiers are equipped to determine lead impedances so that poor connections can be corrected and so that respiratory phase can be sensed.

5 System 100 is used to implement a method 200, illustrated in FIG. 2. ECG electrode sets 110 are attached, at step 202, to collect, at step 204, a first subset of ECG signal data. ECG electrodes 112 are attached, at step 206, to collect, at step 208, a second subset of ECG data. EMI sensors 116, are positioned, at step 210, to collect, at step 212, EMI data. Subject 99 is optionally fitted, at step 214, with sensors 114 which collect, at step 216, data on physiological indicators of REM sleep and autonomic drive status. Data collected from sensors 114 and 116, and ECG electrode sets 110 are monitored, at step 218. When it is determined, in step 220, that EMI is not excessive, and when there is detected REM sleep, at step 222 (via absence of EMG signals), or autonomic fluctuation at step 224 (via heartrate variability analysis), or ischemia at step 226 (via ST segment analysis), full data are recorded, at step 228. The second subset 20 of ECG data, which is collected, at step 208, from a minimum number of electrodes 112 on a minimum number of signal channels 128, is continuously recorded so that a complete record of ECG activity is available for arrhythmia analysis.

25 Computer 102 comprises a signal processing section 302, which receives data from RFE 106, as shown in FIG. 3. Signal processing section 302 divides the incoming data so that secondary ECG data and other data to be continuously recorded is directed along secondary data path 306 and so that primary ECG data and other data to be selectively recorded are directed along primary path 308. The secondary data along secondary data path 306 are received by interface 310 which forwards the received data to data storage 140 via data path 314.

30 Primary data line 308 can be selectively enabled and disabled using a gate 316, which. When gate 316 is disabled, no primary data reaches interface 310. When gate 316 is enabled, interface 310 forwards primary data along with secondary data along path 314 for recording by data storage 140. The status of gate 316 is determined by REM-state detector function 318. Detector 318 receives data pertinent to the determination of REM-state, 35 autonomic fluctuations, and ischemia from signal processor 302 via data path 320. Detector 318 analyzes these data to detect the states of interest. Upon detection of REM sleep, autonomic fluctuations or ischemia, detector 318 transmits a control signal along control line 322, enabling gate 316.

40 In system 100, the ECG data from multiple channels 126 and 128 are combined after analog-to-digital conversion, while an alternative embodiment allows for analog combining of channels prior to conversion to digital form to achieve improved data reduction. Another embodiment of the invention enables the computer 102 to start the recording when incoming data indicate the onset of REM

sleep and stop the recording when incoming data indicate the end of REM sleep, while another alternative embodiment has the recording automatically stopped after a set interval of time, on the order of twenty minutes, the typical duration of REM sleep.

Embodiments appropriate for measuring autonomic drive levels allow for off-line spectral analysis of heart rate variability and covariance analysis of heart rate and respiration both performed on data from ECG electrode sets 110. They also allow for off-line analysis of signals provided by sensors 114 which monitor galvanic skin response or respiration. Sensors 114 may measure respiration using impedance plethysmography or strain gauges. Additional sensors 146 may measure blood pressure using cycled arm cuff or servoed finger cuff. Signals from blood pressure sensors 146 would be transmitted through blood pressure leads 148, and blood pressure signal channels 150 to be processed and analyzed. Assessment of baroreflex sensitivity can be realized by co-analyzing spontaneous blood pressure changes and the associated heart rate fluctuation. A decrease in baroreflex sensitivity indicates susceptibility to unstable cardiac activation in response to autonomic drive modulation. Since this insensitivity often appears after myocardial infarction, a cardiac analyzer with capability for measuring blood pressure along with ECG signals is useful for patients who have suffered heart attacks. Alternatively, when sensors 114 measure respiratory rhythms along with ECG during REM sleep, they are useful in detecting sleep apnea or a tendency toward sudden infant death syndrome.

The present invention provides embodiments in which different numbers of ECG electrode sets are used. Any subset or none of the ECG electrode sets can be constantly recorded. Different numbers of EMI electrode sets can be used for data gating, or means for correction can be employed (adaptive noise cancellation). Different numbers and types of sensors can be recorded for off-line analysis. Data can be recorded in analog or digital form and on magnetic, paper or other media. These and other variations upon and modifications to the described embodiments are provided for by the present invention, the scope of which is limited only by the following claims.

### Claims

1. A cardiac analyzer (100) comprising:  
data collection means (106) for collecting physiological data from an individual, said data collection means having a data channel set of data channels (126, 128, 144) for transmitting a first data set of said physiological data, said first data set including a first ECG data subset
- 5 and a sleep state data subset from which an REM sleep state can be detected;  
recording means (140) for recording at least some of said first data set; and  
a computer (102) coupled to said data collection means and to said recording means, said computer having state detector means (318) to analyze said first data set for indications of a REM sleep state so that said computer causes said recording means to begin recording said first ECG data subset during said REM sleep state.
- 10 2. A cardiac analyzer as recited in Claim 1 wherein said sleep state data subset is ECG data subset.
- 15 3. A cardiac analyzer as recited in Claim 1 wherein said sleep state data subset is from at least one element of the set of instruments consisting of an electro-occulograph, an electromyograph, and an electroencephalograph.
- 20 4. A cardiac analyzer as recited in Claim 1 wherein said state detector means is further capable of analyzing said first data set for indications of autonomic drive fluctuation so that said computer causes said recording means to begin recording in response to said indications of autonomic drive fluctuation.
- 25 5. A cardiac analyzer as recited in Claim 1 wherein said state detector means is further capable of analyzing said first data set for indications of ischemia so that said computer causes said recording means to begin recording in response to said indications of ischemia.
- 30 6. A cardiac analyzer as recited in Claim 1 wherein said collection means further comprises a second data channel (128) for transmitting a second data set of electrocardiographic data so that said computer causes said recording means to continually record said second data set.
- 35 7. A cardiac analyzer as recited in Claim 6 wherein said computer causes said recording means to stop recording said first data set when said state detector means indicates that said REM sleep state is no longer present.
- 40 8. A cardiac analyzer as recited in Claim 6 wherein said computer causes said recording means to stop recording said first data set a fixed period of time after recording of said first data set is begun.
- 45
- 50
- 55

9. A cardiac analyzer as recited in Claim 6 wherein said collection means collects EMI data, said computer having EMI valuation means for evaluating when said EMI data indicates that a EMI threshold is exceeded, said computer causing said recording means to stop recording said first data set when said EMI data indicates that said EMI threshold is exceeded.

10. A cardiac analyzer (100) comprising:

- data collection means (106) for collecting physiological data from an individual, said data collection means having at least a first data channel (126) for transmitting a first data set of said physiological data, said first data set including a first ECG data subset and an autonomic drive data subset from which autonomic drive fluctuation can be detected;
- recording means (140) for recording at least some of said first data set; and
- a computer (102) coupled to said data collection means and to said recording means, said computer having state detector means to analyze said first data set for indications of autonomic drive fluctuation so that said computer causes said recording means to begin recording said first ECG data subset in response to said indications of autonomic drive fluctuation.

11. A method of characterizing cardiac electrical stability in an individual, said method comprising the steps of:

- attaching (202) primary ECG electrode sets to an individual;
- collecting (204) primary ECG signal data through said primary ECG electrode sets;
- monitoring (218) said primary ECG signal data to determine periods during which a REM sleep state of said individual can be detected (222); and
- initiating recording (228) of said primary signal data when said REM sleep state is detected.

12. The method of Claim 11 wherein:

- said attaching step further involves attaching (206) secondary ECG electrode sets to said individual;
- said collecting step further involves collecting (208) secondary signal data through said secondary ECG electrode sets; and
- said recording step further involves recording said secondary ECG signal data continuously.

13. The method of Claim 12 further wherein:

- said attaching step further involves attaching (214) physiological sensors to said individual;
- said collecting step further involves collecting (216) physiological signal data through said physiological sensors;
- said monitoring step further involves monitoring (218) said physiological data so autonomic fluctuation (224) of said individual can be detected and monitoring (218) said primary ECG data so ischemia (226) can be detected; and
- said recording step further involves initiating recording of said primary signal data when autonomic fluctuation is detected and initiating recording of said primary signal data when ischemia is detected.

14. A method of characterizing cardiac electrical stability in an individual, said method comprising the steps of:

- attaching (202) primary ECG electrode sets to an individual;
- collecting (204) primary ECG signal data through said primary ECG electrode sets;
- monitoring (218) said primary ECG signal data to determine periods during which autonomic fluctuations of said individual can be detected (224); and
- initiating recording (228) of said primary signal data when said autonomic fluctuations are detected.

15. A method of characterizing baroreceptor reflex sensitivity in an individual, said method comprising the steps of:

- attaching (202) primary ECG electrode sets to an individual;
- attaching (214) a non-invasive blood pressure sensor to an individual;
- collecting (204) primary ECG signal data through said primary ECG electrode sets;
- collecting (216) blood pressure data through said blood pressure sensor;
- monitoring (218) said primary ECG signal data and said blood pressure data to determine periods during which spontaneous blood pressure changes and the associated heart rate fluctuation occur in said individual; and
- initiating recording (228) of said primary ECG signal data and said blood pressure data when a decrease in baroreflex sensitivity occurs.

## Patentansprüche

1. Ein Herzanalysator (100), mit:  
einer Datensammeleinrichtung (106) zum Sammeln von physiologischen Daten einer Person, wobei die Datensammeleinrichtung einen Datenkanalsatz von Datenkanälen (126, 128, 144) zum Übertragen eines ersten Datensatzes der physiologischen Daten aufweist, wobei der erste Datensatz eine erste EKG-Datenteilmenge und eine Schlaf-Zustandsdatenteilmenge einschließt, aus der ein REM-Schlafzustand bzw. Schlafzustand mit schneller Augenbewegung erfaßt werden kann;  
einer Aufzeichnungseinrichtung (140) zum Aufzeichnen zumindest eines Teils des ersten Datensatzes; und  
einem Computer (102), der mit der Datensammeleinrichtung und mit der Aufzeichnungseinrichtung verbunden ist, wobei der Computer eine Zustandsdetektoreinrichtung (318) aufweist, um den ersten Datensatz bezüglich Anzeichen eines REM-Schlafzustandes zu analysieren, so daß der Computer bewirkt, daß die Aufzeichnungseinrichtung mit dem Aufzeichnen der ersten EKG-Datenteilmenge während des REM-Schlafzustandes beginnt.

2. Ein Herzanalysator nach Anspruch 1, bei dem die Schlafzustandsdatenteilmenge eine EKG-Datenteilmenge ist.

3. Ein Herzanalysator nach Anspruch 1, bei dem die Schlafzustandsdatenteilmenge zumindest von einem Element des Meßgerätsatzes herührt, der aus einem Elektro-Okkulographen, einem Elektromyographen und einem Elektroenzephalographen besteht.

4. Ein Herzanalysator nach Anspruch 1, bei dem die Zustandsdetektoreinrichtung ferner fähig ist, den ersten Datensatz bezüglich Anzeichen einer autonomen Aktivitätsfluktuation zu analysieren, so daß der Computer bewirkt, daß die Aufzeichnungseinrichtung die Aufzeichnung als Reaktion auf die Anzeichen der autonomen Aktivitätsfluktuation beginnt.

5. Ein Herzanalysator nach Anspruch 1, bei dem die Zustandsdetektoreinrichtung ferner fähig ist, den ersten Datensatz bezüglich Anzeichen einer Ischämie zu analysieren, so daß der Computer bewirkt, daß die Aufzeichnungseinrichtung als Reaktion auf die Anzeichen der Ischämie die Aufzeichnung beginnt.

6. Ein Herzanalysator nach Anspruch 1, bei dem die Sammeleinrichtung ferner einen zweiten Datenkanal (128) zum Übertragen eines zweiten Datensatzes von elektrokardiographischen Daten umfaßt, so daß der Computer bewirkt, daß die Aufzeichnungseinrichtung den zweiten Datensatz kontinuierlich aufzeichnet.

7. Ein Herzanalysator nach Anspruch 6, bei dem der Computer bewirkt, daß die Aufzeichnungseinrichtung die Aufzeichnung des ersten Datensatzes beendet, wenn die Zustandsdetektoreinrichtung anzeigt, daß der REM-Schlafzustand nicht länger vorhanden ist.

8. Ein Herzanalysator nach Anspruch 6, bei dem der Computer bewirkt, daß die Aufzeichnungseinrichtung die Aufzeichnung des ersten Datensatzes nach einer festgelegten Zeitperiode, nachdem die Aufzeichnung des ersten Datensatzes begonnen hat, beendet.

9. Ein Herzanalysator nach Anspruch 6, bei dem die Sammeleinrichtung EMI-Daten bzw. elektromagnetische Interferenzdaten sammelt, wobei der Computer eine EMI-Beurteilungseinrichtung aufweist, um zu beurteilen, wann die EMI-Daten anzeigen, daß eine EMI-Schwelle überschritten ist, wobei der Computer bewirkt, daß die Aufzeichnungseinrichtung die Aufzeichnung des ersten Datensatzes anhält, wenn die EMI-Daten anzeigen, daß die EMI-Schwelle überschritten ist.

10. Ein Herzanalysator (100) mit:  
einer Datensammeleinrichtung (106) zum Sammeln physiologischer Daten einer Person, wobei die Datensammeleinrichtung zumindest einen ersten Datenkanal (126) zum Übertragen eines ersten Datensatzes der physiologischen Daten aufweist, wobei der erste Datensatz eine erste EKG-Datenteilmenge und eine autonome Aktivitätsdatenteilmenge einschließt, aus der eine autonome Aktivitätsfluktuation erfaßt werden kann;  
einer Aufzeichnungseinrichtung (140) zum Aufzeichnen zumindest eines Teils des ersten Datensatzes; und  
einem Computer (102), der mit der Datensammeleinrichtung und mit der Aufzeichnungseinrichtung verbunden ist, wobei der Computer eine Zustandsdetektoreinrichtung aufweist, um den ersten Datensatz bezüglich Anzeichen einer autonomen Aktivitätsfluktuation zu analysieren, so daß der Computer bewirkt, daß die Aufzeichnungseinrichtung mit der Aufzeichnung der ersten EKG-Datenteilmenge als Reaktion auf die Anzeichen einer autonomen Aktivitätsfluktuation beginnt.

11. Ein Verfahren zum Charakterisieren einer lektrischen Herzstabilität bei einer Person, wobei das Verfahren folgende Schritte aufweist: Befestigen (202) primärer EKG-Elektrodensätze an einer Person; Sammeln (204) primärer EKG-Signaldaten durch die primären EKG-Elektrodensätze; Überwachen (218) der primären EKG-Signaldaten, um Perioden zu bestimmen, während der ein REM-Schlafzustand bzw. Schlafzustand mit schneller Augenbewegung der Person erfaßt werden kann (222); und Beginnen des Aufzeichnens (228) der primären Signaldaten, wenn der REM-Schlafzustand erfaßt wird.

12. Das Verfahren nach Anspruch 11, bei dem der Befestigungsschritt ferner das Befestigen (206) sekundärer EKG-Elektrodensätze an der Person einschließt; der Sammelschritt ferner das Sammeln (218) der sekundären Signaldaten durch die sekundären EKG-Elektrodensätze einschließt; und der Aufzeichnungsschritt das kontinuierliche Aufzeichnen der sekundären EKG-Signaldaten einschließt.

13. Das Verfahren nach Anspruch 12, bei dem ferner der Befestigungsschritt ferner das Befestigen (214) physiologischer Sensoren an der Person einschließt; der Sammelschritt ferner das Sammeln (216) physiologischer Signaldaten durch die physiologischen Sensoren einschließt; der Überwachungsschritt ferner das Überwachen (218) der physiologischen Daten, so daß eine autonome Fluktuation (224) der Person erfaßt werden kann, und das Überwachen (218) der primären EKG-Daten einschließt, so daß eine Ischämie (226) erfaßt werden kann; und der Aufzeichnungsschritt ferner das Beginnen der Aufzeichnung der primären Signaldaten, wenn eine autonome Fluktuation erfaßt wird, und das Beginnen der Aufzeichnung der primären Signaldaten einschließt, wenn eine Ischämie erfaßt wird.

14. Das Verfahren zum Charakterisieren der elektrischen Herzstabilität bei einer Person, wobei das Verfahren folgende Schritte aufweist: Befestigen (202) primärer EKG-Elektrodensätze an einer Person; Sammeln (204) primärer EKG-Signaldaten durch die primären EKG-Elektrodensätze; Überwachen (218) der primären EKG-Signaldaten, um Perioden zu bestimmen, während denen automatische Fluktuationen der Person erfaßt werden können (224); und Beginnen der Aufzeichnung (228) der primären Signaldaten, wenn die autonomie Fluktuationen erfaßt werden.

15. Das Verfahren zum Charakterisieren der Barorezeptorreflexempfindlichkeit einer Person, wobei das Verfahren folgende Schritte aufweist: Befestigen (202) primärer EKG-Elektrodensätze an einer Person; Befestigen (214) eines nicht-invasiven Blutdrucksensors an einer Person; Sammeln (204) primärer EKG-Signaldaten durch die primären EKG-Elektrodensätze; Sammeln (216) von Blutdruckdaten durch den Blutdrucksensor; Überwachen (218) der primären EKG-Signaldaten und der Blutdruckdaten, um Perioden zu bestimmen, während denen spontane Blutdruckänderungen und die zugeordnete Herzratenfluktuation bei der Person auftritt; und Beginnen der Aufzeichnung (228) der primären EKG-Daten und der Blutdruckdaten, wenn ein Abfall der Baroreflexempfindlichkeit auftritt.

#### Revendications

1. Analyseur cardiaque (100) comprenant: des moyens de collecte de données (106), pour recueillir des données physiologiques d'un individu, lesdits moyens de collecte de données comportant un ensemble de canaux de données, constitué de canaux de données (126, 128, 144) destinés à transmettre un premier ensemble de données desdites données physiologiques, ledit premier ensemble de données comportant un premier sous-ensemble de données d'ECG et un sous-ensemble de données d'état de sommeil duquel un état de mouvement rapide de l'oeil lors du sommeil peut être détecté; des moyens d'enregistrement (140), pour enregistrer au moins une partie dudit premier ensemble de données; et un ordinateur (102) couplé auxdits moyens de collecte de données et auxdits moyens d'enregistrement, ledit ordinateur comportant des moyens de détection d'état (318) pour analyser ledit premier ensemble de données en ce qui concerne des indications d'un état de mouvement rapide de l'oeil lors du sommeil, de façon que ledit ordinateur provoque le commencement d'enregistrement par lesdits moyens d'enregistrement, dudit premier sous-ensemble de données d'ECG pendant ledit état de mouvement rapide de l'oeil lors du sommeil.

2. Analyseur cardiaque selon la revendication 1, dans lequel ledit sous-ensemble de données d'état de sommeil est un sous-ensemble de données d'ECG. 5

3. Analyseur cardiaque selon la revendication 1, dans lequel ledit sous-ensemble de données d'état de sommeil provient au moins d'un élément de l'ensemble d'appareils constitués par un électroocculographe, un électromyographe, et un électroencéphalographe. 10

4. Analyseur cardiaque selon la revendication 1, dans lequel lesdits moyens de détection d'état sont capables en outre, d'analyser ledit premier ensemble de données en ce qui concerne les indications de fluctuation de commande autonome, de façon que ledit ordinateur provoque le commencement de l'enregistrement par lesdits moyens d'enregistrement en réponse auxdites indications de fluctuation de commande autonome. 15

5. Analyseur cardiaque selon la revendication 1, dans lequel lesdits moyens de détection d'état sont capables en outre, d'analyser ledit premier ensemble de données en ce qui concerne les indications d'ischémie, de façon que ledit ordinateur provoque le commencement de l'enregistrement par lesdits moyens d'enregistrement en réponse auxdites indications d'ischémie. 20

6. Analyseur cardiaque selon la revendication 1, dans lequel lesdits moyens de collecte comprennent en outre un second canal de données (128) pour transmettre un second ensemble de données, constitué de données électrocardiographiques de façon que ledit ordinateur provoque l'enregistrement continu par lesdits moyens d'enregistrement dudit second ensemble de données. 25

7. Analyseur cardiaque selon la revendication 6, dans lequel ledit ordinateur provoque l'arrêt de l'enregistrement dudit premier ensemble de données par lesdits moyens d'enregistrement lorsque lesdits moyens de détection d'état indiquent que ledit état de mouvement rapide de l'oeil lors du sommeil n'est plus présent. 30

8. Analyseur cardiaque selon la revendication 6, dans lequel ledit ordinateur provoque l'arrêt de l'enregistrement dudit premier ensemble de données par lesdits moyens d'enregistrement, au bout d'une durée fixe après le début de l'enregistrement dudit premier ensemble de données. 35

9. Analyseur cardiaque selon la revendication 6, dans lequel lesdits moyens de collecte recueillent les données d'EMI, ledit ordinateur comportant des moyens d'évaluation d'EMI pour évaluer le moment où les données d'EMI indiquent qu'un seuil d'EMI est dépassé, ledit ordinateur provoquant l'arrêt de l'enregistrement dudit premier ensemble de données par lesdits moyens d'enregistrement lorsque lesdites données d'EMI indiquent que ledit seuil d'EMI est dépassé. 40

10. Analyseur cardiaque comprenant:  
des moyens de collecte de données (106), pour recueillir des données physiologiques d'un individu, lesdits moyens de collecte de données comportant au moins un premier canal de données (126) pour transmettre un premier ensemble de données desdites données physiologiques, ledit premier ensemble de données comportant un premier sous-ensemble de données d'ECG et un sous-ensemble de données de commande autonome depuis lequel une fluctuation de commande autonome peut être détectée;  
des moyens d'enregistrement (140), pour enregistrer au moins une partie dudit premier ensemble de données; et  
un ordinateur (102) couplé auxdits moyens de collecte de données et auxdits moyens d'enregistrement, ledit ordinateur comportant des moyens de détection d'état pour analyser ledit premier ensemble de données en ce qui concerne des indications de fluctuations de commande autonome, de façon que ledit ordinateur provoque le commencement de l'enregistrement par lesdits moyens d'enregistrement dudit premier sous-ensemble de données d'ECG en réponse auxdites fluctuations de commande autonome. 45

11. Procédé de caractérisation de la stabilité électrique cardiaque sur un individu, ledit procédé comprenant les étapes de:  
fixation (202) d'ensembles d'électrodes primaires d'ECG à un individu;  
collecte (204) des données des signaux d'ECG primaires par lesdits ensembles d'électrodes primaires d'ECG;  
surveillance (218) desdites données de signaux d'ECG primaires pour déterminer les périodes pendant lesquelles un état de mouvement rapide de l'oeil lors du sommeil dudit individu peut être détecté (222); et  
initialisation d'enregistrement (228) desdites données de signaux primaires lorsque l'état de mouvement rapide de l'oeil lors du sommeil est détecté. 50 55

12. Procédé selon la revendication 11, dans lequel:  
 ladite étape de fixation implique en outre la fixation (206) d'ensembles d'électrodes secondaires d'ECG audit individu;  
 ladite étape de collecte implique en outre la collecte (208) de données de signaux d'ECG secondaires par lesdits ensembles d'électrodes secondaires d'ECG; et  
 ladite étape d'enregistrement implique en outre l'enregistrement continu desdites données de signaux d'ECG secondaires. 5

13. Procédé selon la revendication 12, dans lequel:  
 ladite étape de fixation implique en outre la fixation (214) de capteurs physiologiques audit individu;  
 ladite étape de collecte implique en outre la collecte (216) de données de signaux physiologiques par lesdits capteurs physiologiques; 10  
 ladite étape de surveillance implique en outre la surveillance (218) desdites données physiologiques, de façon que la fluctuation autonome (224) dudit individu puisse être détectée, et la surveillance (218) desdites données d'ECG primaires, de façon que l'ischémie (226) puisse être détectée; et  
 ladite étape d'enregistrement implique en outre le commencement de l'enregistrement desdites données de signaux primaires lorsque la fluctuation autonome est détectée, et le commencement de l'enregistrement desdites données de signaux primaires lorsque l'ischémie est détectée. 15

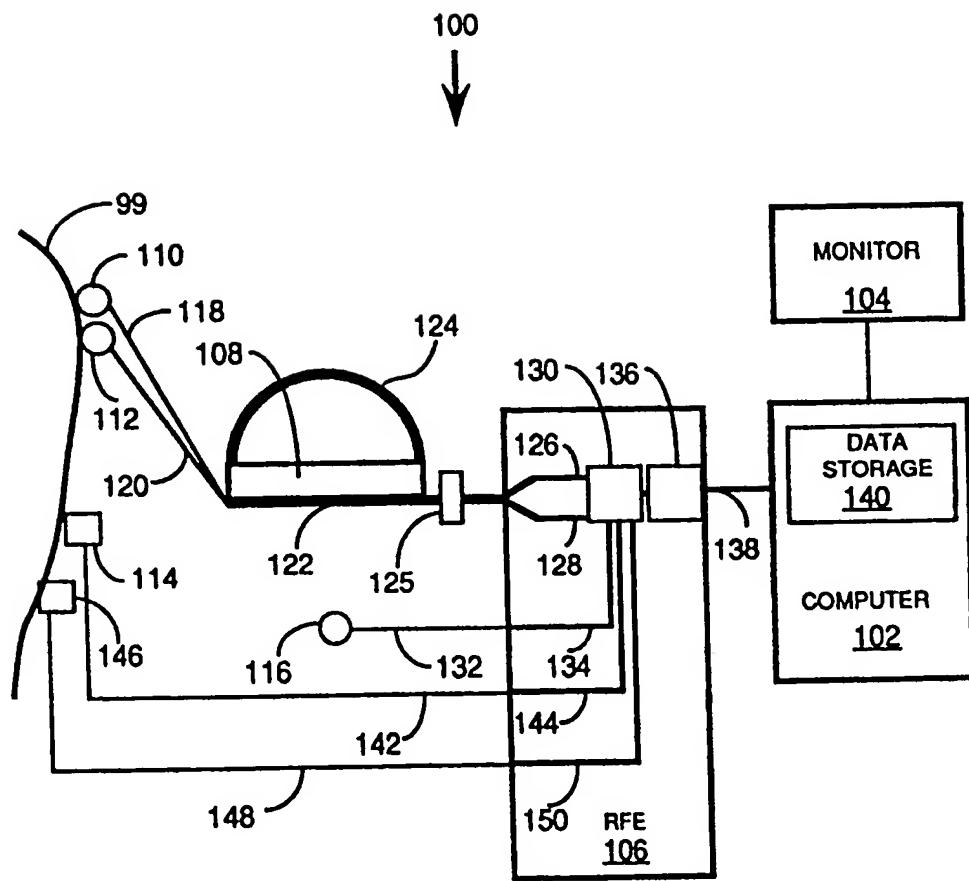
14. Procédé de caractérisation de la stabilité électrique cardiaque sur un individu, ledit procédé comprenant les étapes de:  
 fixation (202) d'ensembles d'électrodes primaires d'ECG à un individu;  
 collecte (204) des données de signaux d'ECG primaires par lesdits ensembles d'électrodes primaires d'ECG; 20  
 surveillance (218) desdites données de signaux d'ECG primaires pour déterminer les périodes pendant lesquelles les fluctuations autonomes dudit individu peuvent être détectées (224); et  
 initialisation de l'enregistrement (228) desdites données de signaux primaires lorsque lesdites fluctuations autonomes sont détectées. 25

15. Procédé de caractérisation de sensibilité de réflexes de barorécepteur sur un individu, ledit procédé comprenant les étapes de:  
 fixation (202) d'ensembles d'électrodes primaires d'ECG à un individu; 30  
 fixation (214) d'un capteur de tension artérielle non destructeur à un individu;  
 collecte (204) des données de signaux d'ECG primaires par lesdits ensembles d'électrodes primaires d'ECG;  
 collecte (216) des données de tension artérielle par ledit capteur de tension artérielle; 35  
 surveillance (218) desdites données de signaux d'ECG primaires et desdites données de tension artérielle pour déterminer les périodes pendant lesquelles la tension artérielle spontanée varie et les fluctuations du rythme cardiaque associées se produisent chez ledit individu; et  
 initialisation de l'enregistrement (228) desdites données de signaux d'ECG primaires et desdites données de tension artérielle lorsqu'une diminution de la sensibilité des baroréflexes se produit. 40

45

50

55



*Figure 1*

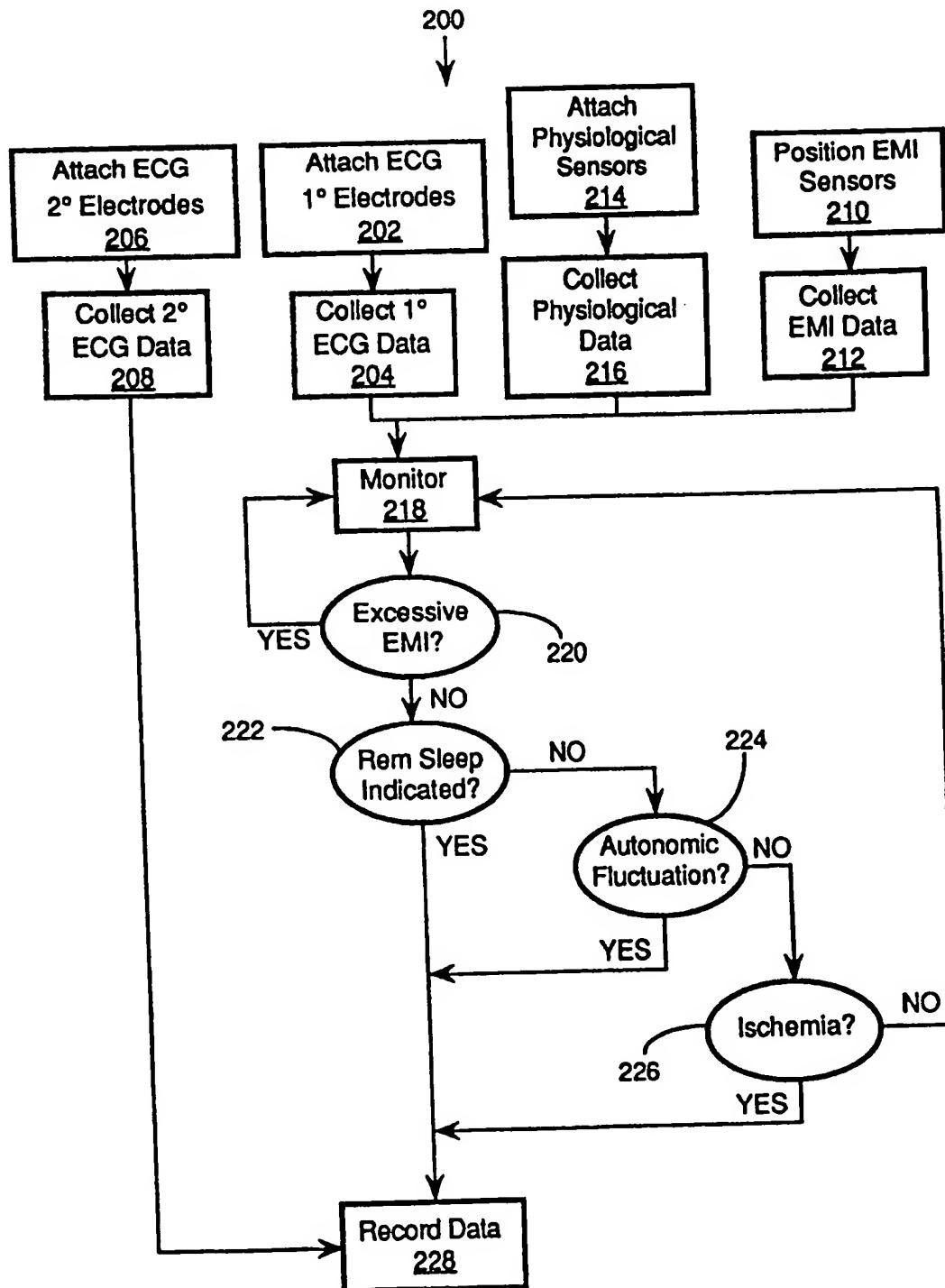


Figure 2

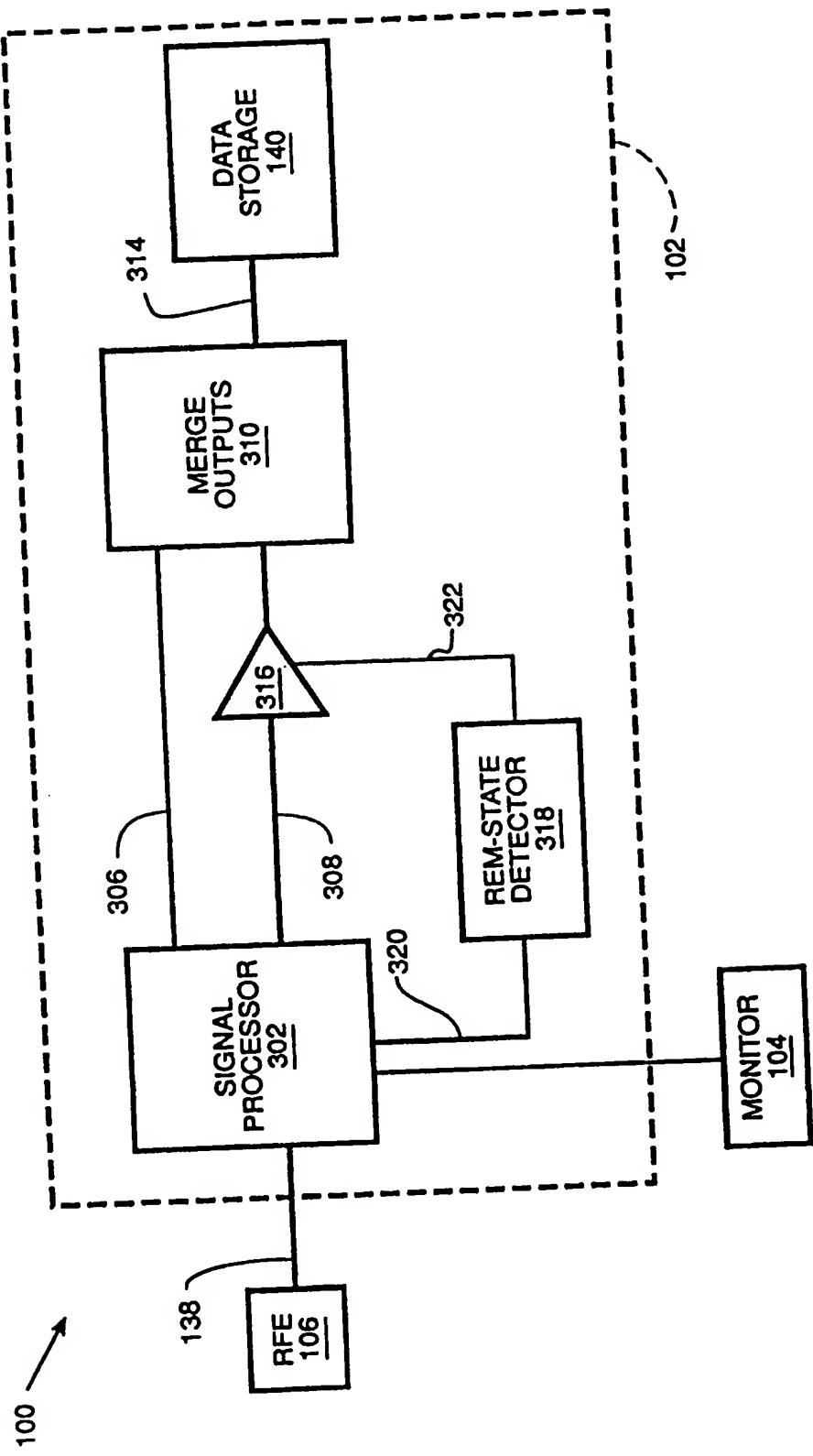


Figure 3